Wavefront-Guided LASIK for the Correction of Primary Myopia and Astigmatism: A Report by the American Academy of Ophthalmology

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Objective.—To describe wavefront-guided (WFG) LASIK for the primary treatment of low to moderate levels of myopia and astigmatism and to examine the evidence on the safety and effectiveness of the procedure in comparison with conventional LASIK.

Methods.—Literature searches conducted in 2004, 2005, 2006, and 2007 retrieved 209 unique references from the PubMed and Cochrane Library databases. The panel selected 65 articles to review, and of these, chose 45 articles that they considered to be of sufficient clinical relevance to submit to the panel methodologist for review. During the review and preparation of this assessment, an additional 2 articles were included. A level I rating was assigned to properly conducted, well-designed, randomized clinical trials; a level II rating was assigned to well-designed cohort and case-controlled studies; and a level III rating was assigned to case series, case reports, and poorly designed prospective and retrospective studies. In addition, studies that were conducted by laser manufacturers before device approval (premarket approval) were reviewed as a separate category of evidence.

Results.—The assessment describes studies reporting results of WFG LASIK clinical trials, comparative trials, or both of WFG and conventional LASIK that were rated level II and level III. There were no studies rated as level I evidence. Four premarket approval studies conducted by 4 laser manufacturers were included in the assessment. The assessment did not compare study results or laser platforms because there were many variables, including the amount of follow-up, the use of different microkeratomes, and the level of preoperative myopia and astigmatism.

Conclusions.—There is substantial level II and level III evidence that WFG LASIK is safe and effective for the correction of primary myopia or primary myopia and astigmatism and that there is a high level of patient satisfaction. Microkeratome and flap-related complications are not common but can occur with WFG LASIK, just as with conventional LASIK. The WFG procedure seems to have similar or better refractive accuracy and uncorrected visual acuity outcomes compared with conventional LASIK. Likewise, there is evidence of improved contrast sensitivity and fewer visual symptoms, such as glare and halos at night, compared with conventional LASIK. Even though the procedure is designed to measure and treat both lower- and higher-order aberrations (HOAs), the latter are generally increased after WFG LASIK. The reasons for the increase in HOA are likely multifactorial, but the increase typically is less than that induced by conventional LASIK. No long-term assessment

TABLE 2.—Summary of Premarket Wavefront-Guided LASIK Results Submitted by Manufacturers to the Food and Drug Administration for the Treatment of Primary Myopia and Astigmatism (Level II Evidence)

Year Approved	Laser	Follow-up Reported (mos)	No. of Eyes Reported at 6 mos	Optical Zone (mm)	Ablation Zone (mm)	Preoperative Sphere (D), Range	Preoperative Cylinder (D), Range	Postoperative Manifest Spherical Equivalent within 0.5 D (%)	Cylinder Correction Ratio (Surgically Induced Refractive Correction/ Intended Refractive Correction)	Uncorrected Visual Acuity ≥20/20 (%)	Uncorrected Visual Acuity ≥ Preoperative Best Spectacle-Corrected Visual Acuity (%)	Loss of Best Spectacle-Corrected Visual Acuity ≥2 Lines (%)	Time to Stability (mos)
2003	AMO VISX S4 & WaveScan WaveFront System (Santa Clara, CA)	12	277	6.0	8.0	0 to −6.0	0 to −3.0	90.3	NR	93.9	NR	0	3
2003	Bausch & Lomb Technolas 217*z* (Rochester, NY)	6	340	5.75–7.24	7.5–9.0	0 to −7.0	0 to −3.0	75.9	1.0	91.5	78	0.6	3
2004	Alcon LADARVision (Fort Worth, TX)	6	232	6.5	9.0	0 to −8.0	0 to −4.0	80.2	1.03	84.1	67.2	0	3
2006	WaveLight Allegretto with the Allegro analyzer (WaveLight AG, Erlangen, Germany)	6	166	6.5	9.0	0 to −7.0	0 to −3.0	94.6	1.15	93.4	81.1	0	3

D = diopters; NR = not reported.

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of WFG LASIK was possible because of the relatively short follow-up (12 months or fewer) of most of the studies reviewed (Table 2).

▶ The Ophthalmic Technology Assessments (OTA) were created by the American Academy of Ophthalmology (AAO) many years ago to provide an unbiased, evidence-based evaluation of new technology for the AAO membership. As a matter of disclosure, I was the Chair of the AAO-OTA for refractive surgery several years ago and was responsible for numerous Assessments, including laser in situ keratomileusis (LASIK), for myopia and astigmatism. A typical OTA takes about a year to produce. There is tremendous support from the AAO staff to identify appropriate articles and have them reviewed by a methodologist before members of the OTA committee review them. This group then writes the document and then generally meets face to face for a weekend to edit the assessment. It is then circulated to the relevant subspecialty societies for their input and revised as needed before being approved by the AAO board and published in *Ophthalmology*.

While not an issue for LASIK, the OTAs are often cited by various ophthalmic groups to justify the use of certain new technologies to insurance companies to get these services covered at an appropriate level.

The conclusions of this OTA are fairly straightforward. Wavefront-guided LASIK for myopia and astigmatism has similar or slightly better refractive results when compared with conventional LASIK. It was also found to result in fewer glare and halo symptoms and better contrast sensitivity than conventional LASIK. Although it does generally induce some higher order aberrations compared with preoperative levels, custom wavefront LASIK induced fewer higher order aberrations than conventional LASIK. The main caveat was that their conclusions were based on relatively short, 12-month or less follow-up (see Table 2). Having done wavefront LASIK for over 4 years, my sense is that these results are holding up nicely.

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Corneal wavefront-guided photorefractive keratectomy in patients with irregular corneas after corneal refractive surgery

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Purpose.—To evaluate the corrective potential of corneal wavefront-guided photorefractive keratectomy (PRK) in patients with high levels of corneal aberrations and symptoms after previous corneal refractive surgery.

Setting.—Vissum-Instituto de Oftalmológico de Alicante, Alicante, Spain.

Methods.—This study comprised 25 eyes (20 patients) that had 1 or more previous unsuccessful keratorefractive procedure. All eyes had